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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,803	03/07/2002	Krishnan Chari	83494D-W	3394

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/092,803	Applicant(s) CHARI ET AL.	
	Examiner Jennifer Kolb Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>na</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30, drawn to a method of making a microarray, classified in class 427, subclass 2.1.
- II. Claim 31, drawn to a microarray, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as applying the microspheres, receiving layer material, and crosslinking agent together and/or in the absence of a solvent, such as in a laminate.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Ms. Wells on 10/14/2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-30. Affirmation of this election must be made by applicant in replying to this Office action. Claim 31 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

8. The information disclosure statement (IDS) contains 2 references which are patent applications. It is not U.S. practice to print applications as references cited on the front of issued patents, therefore, these references have been crossed-through by Examiner. However, the contents of these applications have been considered, and at the time of their issue, can be included as patent references cited in the instant case.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guire et al. (US 2003/0073086 A1).

Guire teaches a method of making microarrays by immobilizing microparticles on support substrates (abstract).

Guire inherently teaches "providing a support". Guire teaches first coating the substrate with a compound (or compounds) that is used to immobilize spherical microparticles, or microspheres, as required by Applicant, onto the support substrate (P 0038-0039).

In one embodiment, Guire teaches that microparticles can be immobilized by first coating the support with a polymer *prior to* or during the step of coating with the microparticles (P0088). It is the "prior to" teaching upon which Examiner relies to meet the limitation of Applicant's claim 1 requiring a receiving layer to be coated onto the support prior to the microparticles. Guire teaches the use of polyvinyl alcohol as the immobilization/receiving polymer. This polymer is a "gelling agent", as defined on page 6 of the instant specification and is therefore "capable of undergoing sol/gel transition", as required by the claim.

Guire teaches that the polymer is treated to crosslink the polymer *after* application of the microparticles, to immobilize the microparticles therein (P0096-0097). A crosslinking agent may be used. While Guire goes on to teach an example of the above method in which polymer is supplied with the microparticles in a slurry, Examiner notes that she has relied upon the embodiment in which the polymer is applied *before* the microparticles, in which case, since Guire teaches crosslinking the polymer after the application of the microparticles, it would have been required to put the crosslinking agent taught by Guire in either the polymer coating or the microparticle coating layer when the polymer is coated first, as allowed by Guire. However, Guire does not

specifically teach in which layer the crosslinking agent is applied. Therefore, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to select the use of crosslinking agent in the microparticle solution from the narrow choices of polymer solution and microparticle solution with the expectation of successful results. Since crosslinking does not occur until after the microparticles are applied, it would have been obvious to apply the crosslinking agent with the microparticles of the second layer. Additionally, Example 2 teaches coating a solution of microparticles in the presence of a crosslinking agent onto a biotinylated substrate, which is cited to teach the compatibility of a microparticle solution with a crosslinking agent.

The microparticles become trapped in the non-cross-linked receiving layer (P0155, line 5).

The polymer is crosslinked by activating the crosslinking agent, thus creating the sol/gel transition required by Applicant.

The Examples teach drying which would remove the solvents and liquids of the microparticle slurry, thus removing the "carrier fluid" as required by Applicant.

Regarding claim 3, immobilization is preserved.

Regarding claim 4, Guire does not teach a microparticle coating mechanism, however, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply the microparticle slurry using knife or blade coating, or the like, in order to provide a uniform layer of microparticles on the support substrate. Due to the viscosity

of such a slurry coating, with particles therein, simple pouring may not render a uniform coating. The use of knife or blade coating to yield such a uniform coating would have been obvious to an ordinary artisan in the coating field.

The support of Guire may be glass, polyethylene terephthalate, or plastic (P0036), among others, as required by claim 5, some of which are flexible, as required by claim 6.

The microspheres of Guire may bear bioactive sites to interact chemically with, for example, nucleic acids, as required by claims 7-8 and 12-16 (P0023).

The above method forms a random pattern, as required by claim 9 (abstract).

The receiving layer and support do not necessarily interact with the microspheres (P36, 85, and throughout), as required by claims 10-11 and 30.

Throughout, Guire teaches that the microsphere is made up of a unique pair (P33), qualifying as a "signature", as required by claim 17.

Guire's microspheres may be 100 nm –100 μ m (P39), overlapping the ranges claimed by Applicant in claims 18-20.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Guire's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Regarding claims 21-23, Guire does not teach a microsphere concentration, however it is Examiner's position that it would have been within the skill of an ordinary artisan to optimize the concentration of the microspheres for a particular end use. Since this technology is useful in detecting analytes in a sample, a higher concentration would provide, perhaps, more accurate results. An ordinary artisan would weigh accuracy versus cost to optimize the concentration necessary for a suitable product.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claims 24-26, the microspheres of Guire may be polystyrene (P58), are prepared by emulsion polymerization (P55), as required by claim 29, and have the reactive groups required by Applicant in claim 27 (P63).

Regarding the weight percent of crosslinking agent used with the microspheres, Guire does not specifically teach this limitation of claim 28. However, it is Examiner's position that the amount of this agent would have been determined by an ordinary artisan

desiring to create a specific amount of crosslinking. Determination of optimum cause effective variables would have been obvious for those reasons outlined above.

13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guire in view of Nova (US 6,340,588 B1).

Guire teaches that which is disclosed above, specifically a receiving/immobilization layer of polyvinyl alcohol. Additionally, Guire teaches that this layer may be made of natural polymers, such as proteins, avidin, biotin, polydextrans, and the like, but Guire fails to specifically teach the use of gelatin.

Nova teaches a method of coating matrix materials on supports with bioactive agents, similar to Guire, with a matrix material that can be selected from natural materials such as cellulose, gelatin, and dextran (col. 33, lines 35-65).

Since Guire teaches a receiving layer of polyvinyl alcohol or polydextrans and Nova teaches a receiving layer for use in a similar method consisting of dextran or gelatin, Nova would have reasonably suggested the use of gelatin in the method of Guire. It would have been obvious to one of ordinary skill in the art to use the natural polymer of Nova as the natural polymer in Guire with the expectation of successful results since Nova teaches the interchangeability of gelatin for dextran, with dextran being suitable for the method of Guire.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
October 20, 2003